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CHPA Comments on House Bill 4316

Members of the Judiciary Committee:

Thank you for the opportunity to comment on H.B. 4316. The Consumer Healthcare Products Associations (CHPA) is the 128-year-old trade association representing manufacturers of over-the-counter medicines and dietary supplements. H.B. 4316 would repeal the ability of medicine manufacturers to use the legitimate approval of the United States Food and Drug Administration (FDA) as a defense in product liability suits.

Repealing the existing government standards defense for medicine manufacturers would allow for unnecessary and costly litigation even in cases where manufacturers have met FDA's stringent safety and effectiveness requirements. Our member companies already incur very high costs to defend against the filing, and even the threat, of frivolous lawsuits, and to cover excessive insurance costs.

All pharmaceutical products—including nonprescription, over-the-counter (OTC) medicines—must meet strict FDA standards for safety and efficacy before they can be marketed. The drug approval process is lengthy and rigorous. In addition, having a single federal agency approve medicines for safe use is a critical component of our health care system, and should not be undermined by allowing damage awards from juries applying ad hoc standards to FDA-approved medicines.

The government standards defense is a very reasonable way of recognizing the importance of FDA's regulation of medicines. Yet the existing government standards defense provision also contains important plaintiff protections. The defense is not viable where pharmaceutical manufacturers have withheld or misrepresented information from the FDA during the approval process, or in cases of bribery.

CHPA urges the Michigan Legislature to maintain the government standards defense in pharmaceutical products liability cases in order to maintain a just and efficient liability system.

Respectfully submitted by Mandy Hagan, Director, State Government Relations

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